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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/619,840	07/14/2003	Douglas James Barker	N1388-025	7626
32905	7590	10/21/2005		
JONDLE & ASSOCIATES P.C. 858 HAPPY CANYON ROAD SUITE 230 CASTLE ROCK, CO 80108			EXAMINER BUI, PHUONG T	
			ART UNIT	PAPER NUMBER
			1638	

DATE MAILED: 10/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/619,840	Applicant(s) BARKER, DOUGLAS JAMES	
	Examiner Phuong T. Bui	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2/26/04</u> . | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

1. Claims 1-21 are pending and are examined in the instant Office action.

Drawings

2. No drawings have been submitted in the instant application.

Claim Rejections - 35 USC § 112, 2nd paragraph

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The ATCC Accession Number must be filled in where appropriate to clearly provide the identifying characteristics for Applicant's corn line designation. Compliance with this requirement may be held in abeyance until a deposit is made.

In claim 2, where the part is a seed, the Office interprets it to be the seed that is representative of the deposited seed.

In claim 7, it is suggested "the cells or protoplasts of the tissue culture being" be amended to "said tissue culture is obtained" to further define the claimed tissue culture and correct the lack the antecedence for "protoplasts". Also, "A" should be amended to "The" for proper dependency language.

In claim 13, "collection of seed" should be amended to "collection of seeds".

In claim 14, "decreased" is a relative term lacking a comparative basis.

In claims 15-17, it is unclear how the "derived" plant of (b) is different from those of (c)-(e). It is unclear what is being retained in the "SE8505-derived", the "further SE8505-derived" and the "additional SE8505-derived" plants.

Claims 20-21 are incomplete method claims because they do not recite sufficient process steps that result in "developing a corn plant in a corn plant breeding program using plant breeding techniques" as set forth in the preamble.

Clarification and/or correction of all above issues are required.

Claim Rejections - 35 USC § 112, 1st paragraph, deposit requirement

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-21 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Since the seed claimed is essential to the claimed invention, it must be obtainable by a reproducible method set forth in the specification or otherwise be readily available to the public. If a seed is not so obtainable or available, a deposit thereof may satisfy the requirements of 35 U.S.C. 112. The specification does not disclose a reproducible process to obtain the exact same seed in each occurrence and it is not apparent if such a seed is readily available to the public. It is noted that Applicant intends to deposit the claimed seed at the ATCC, but there is no indication that the seed has been deposited and there is no indication in the specification as to

public availability. If the deposit of the seed is made under the terms of the Budapest Treaty, then an affidavit or declaration by the Applicant, or a statement by an attorney of record over his or her signature and registration number, stating the seed will be irrevocably, and without restriction or condition, released to the public upon the issuance of a patent would satisfy the deposit requirement made herein. A minimum deposit of 2500 seeds is considered sufficient in the ordinary case to assure availability through the period for which a deposit must be maintained.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809, Applicant may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number showing that

- (a) during the pendency of the application, access to the invention will be afforded to the Commissioner upon request;
- (b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
- (c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the enforceable life of the patent, whichever is longer;
- (d) the viability of the biological material at the time of deposit will be tested (see 37 CFR 1.807); and
- (e) the deposit will be replaced if it should ever become unviable.

The deposit information in the specification does not fully comply with the deposit requirements as set forth in 37 CFR 1.801-1.809 because a proper deposit has not been made; and Applicant failed to state that the deposit will be made in compliance with 37 CFR 1.801-1.809.

Claim Rejections - 35 USC § 112, 1st paragraph, written description

7. Claims 10-12, 15-18 and 20-21 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claimed invention lacks written description under current written description guidelines. The claims are drawn to corn progeny plants having undisclosed identifying characteristics whereby only one parent in the first cross is known, and none of the parents in any of the subsequent crosses are known. The claims are also drawn to methods of producing F2 and further descendants of F2. The claims are further drawn to a plant containing unidentified transgenes and a method for producing a progeny plant containing unidentified transgenes. Applicant should note that no identifying characteristics are set forth even for the F1 progeny. If the claimed F1 plant itself cannot be identified by characteristics clearly disclosed in the specification, then it is not even possible to determine whether a plant of unknown parentage is or is not covered by the claim. Thus, F1 progeny plants which are not disclosed by any identifying characteristics are not considered to be possessed by Applicant. There is insufficient relevant identifying characteristics to allow one skilled in the art to

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predictably determine the genomic structure or phenotypic characteristics of the plant obtained at each level of crossing or at each generation, absent further guidance. The breeding techniques encompass recurrent selection, backcrossing, pedigree breeding, restriction fragment length polymorphism enhanced selection, genetic marker enhanced selection, transformation, and combinations thereof. Each of these breeding techniques would result in a structurally and phenotypically different plant. Over an undetermined number of generations, the identifying characteristics for each generation become highly unpredictable, especially in view of the fact that none of the identifying characteristics of the progeny plants are disclosed in the specification or set forth in the claims. Additionally, in the method claims, neither the starting materials nor the end product is adequately described. Applicant should note that methods which generate F1 are adequately described because the F0 parent is adequately described, and crossing an F0 parent with another parent to select for particular traits or characteristics in the F1 progeny plants is routine in the art. However, in methods to generate F2, no traits or characteristics are disclosed for the F1 parent, as indicated above. The disclosure of F1 traits is essential to the claimed invention since the F1 parent is required to generate F2 progeny plants. Thus, these methods would involve crossing two parents having unknown characteristics to generate F2 progeny plants having unknown characteristics. This same unpredictability is applicable to a plant containing unidentified transgenes and using conventional breeding to generate plants containing transgenes. The deposited seed has a defined set of genes and corresponding traits, and it is unpredictable how unidentified transgenes when introduced into a plant would

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alter the genetic makeup of the deposited seed and affect the genotype and phenotype of the resulting transformed plant. If a transgene is incompatible with another introduced transgene or is incompatible with a gene(s) of the deposited seed, it is unclear what the resulting genetic makeup of the claimed transformed plant is. Claim 15 does not provide any identifying characteristics for the parent plants or the resultant seed that one must select for before one can proceed to the next step. Accordingly, there is a lack of adequate description for the claimed progeny plants, methods for generating F2 and subsequent progeny plants and plants containing transgenes, and in view of the level of knowledge and skill in the art, one skilled in the art would not recognize from the disclosure that Applicant was in possession of the claimed invention at the time of filing. Accordingly, the claimed invention lacks adequate written description under current written description guidelines (see Written Description Requirement published in Federal Register/ Vol. 66, No. 4/ Friday, January 5, 2001/ Notices; p. 1099-1111).

Claim Rejections - 35 USC § 112, enablement

8. Claims 15-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claim 15 encompasses a method to introduce a trait from a donor parent into the inbred line, most likely by outcrossing followed by backcrossings. However, the method encompasses at least nine outcrossings and no backcrossing. Even though the

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art recognizes that backcrossings must be included to regain the parental traits, it is unpredictable how many backcrossings are necessary for the particular traits desired.

Murray et al. (Proceedings of the 43rd Annual Corn and Sorghum Research Conference, Vol. 43, pp.72-87, 1988 (U)) teaches the failure to obtain any variety-specific molecular markers in six different corn inbreds (p79); and linkage drag in corn results in 10% rather than 1% of the donor parent genome following ten backcrosses (pp. 82-84). It is unlikely that zero backcrossing as indicated by the claims would be sufficient, but it is unclear how many would be necessary to add a donor trait.

Accordingly, it is unlikely that the method set forth in this claim would result in a plant having all of the physiological and morphological traits of the deposited variety and one additional trait as encompassed by the claims. Applicant provided no guidance as to how the problems set forth by Murray would be overcome. The claims are not limited to any particular trait that can be reliably and predictably introduced into the deposited variety without additional undesirable traits from the donor parent. Applicant provided no working example of a converted plant having a new trait by the claimed method. Accordingly, Applicant has not enabled the claimed invention.

Claim Rejections - 35 USC § 102 and 35 USC § 103

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 10-11, 16 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Stangland (US Pat. No. 6372969 (A)). The prior art teaches a corn plant which shares some of the characteristics disclosed for the deposited variety including glume, anther, silk, cob and kernel color (Table 6). While the corn variety of the prior art has a different line designation from the corn variety of the instant application, there are insufficient identifying characteristics set forth in the claims to distinguish the claimed plants from those of the prior art. Even at the F1 progeny level, no identifying characteristics are recited to distinguish Applicant's F1 plants from those of the prior art. The claims do not specifically recite a plant whereby all of the physiological and morphological characteristics of the SE8505 parent are retained. The methods used to produce the claimed plants involve an undetermined number of crosses and not all of the distinguishing characteristics of the SE8505 parent from the initial cross are necessarily retained. None of the identifying features which distinguish Applicant's plants from those of the prior art are set forth (see written description rejection above). The method of producing the plant, namely using corn SE8505 as the first parent during multiple generations and crosses, would not confer a unique property to the resultant corn which would distinguish it from the prior art corn, particularly if the claimed breeding method

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was followed by multiple generations of backcrossing to a non-SE8505 parent.

Accordingly, the claimed invention is anticipated by, or in the alternative, is obvious in view of the prior art. See *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985), which teaches that a product-by-process claim may be properly rejected over prior art teaching the same product produced by a different process, if the process of making the product fails to distinguish the two products. Since the Patent Office does not have the facilities to examine and compare the plant of Applicant's with that of the prior art, the burden of proof is upon the Applicant to show an unobvious distinction between the claimed plant and the plant of the prior art. See *In re Best*, 562F.2d 1252, 195 USPQ 430 (CCPA 1977).

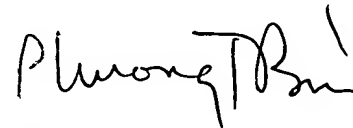
Conclusion

11. No claim is allowed.
12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong T. Bui whose telephone number is 571-272-0793.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on 571-272-0745. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Phuong T. Bui
Primary Examiner
Art Unit 1638

10/17/05

10/14/05